REMARKS

Upon entry of this amendment, claims 2, 5, and 17-21, will be canceled without prejudice to or disclaimer of the subject matter recited therein; and claims 1, 3, 6, and 11 will be amended. Accordingly, claims 1, 3, 4, 6-16, and 22-28 will be pending. Claims 1 and 3 are independent claims. The Office indicates claims 22-28 are deemed withdrawn, as allegedly directed to a non-elected invention.

Applicant notes that claims that recited non-elected subject matter have been maintained, pending rejoinder.

Reconsideration and allowance of the application are respectfully requested.

Interview Summary

On May 9, 2006, Applicant's representative, Sean Myers-Payne, conducted an interview with Examiners Daniel Kolker and Robert Hayes. In the interview, Applicant's representative pointed out that Nakamura et al. does not specifically disclose a composition including all of the elements of Applicant's claimed invention. It was pointed out that Nakamura et al. includes an Example 1, which the Office had specifically relied upon, that discloses 1 mg HGF, 100 ml of phosphate buffer, 0.15 M NaCl, but that this Example does not disclose arginine (or lysine, histidine, glutamine, proline, glutamic acid, or aspartic acid). Applicant's representative pointed out that the disclosure of arginine, relied upon by the Office Action, was in a separate part of the Nakamura et al. document, and that that disclosure was of *optional* additives.

Nakamura et al., it was pointed out by Applicant's representative, does not include arginine in its examples.

Examiners Kolker and Hayes maintained the position that the entire Nakamura et al. disclosure anticipated Applicants' claimed invention.

No agreement was reached.

Claim Objections

The Office Action objects to claims 1, 3, 4, and 6 for reciting non-elected subject matter. In response, Applicant notes that the non-elected subject matter has been kept in the claims, as it is subject to possible rejoinder.

Claim Rejections – 35 U.S.C. § 112

The Office Action rejects claim 11 under 35 U.S.C. § 112, second paragraph, as allegedly indefinite, for referring to a canceled claim. In response, Applicant has amended claim 11 to refer to claim 1.

Applicant respectfully requests withdrawal of the rejection.

Claim Rejections – 35 U.S.C. § 102 and 103

The Office Action maintains the rejections of claims 1, 3, 4, 6-9, and 12-15 under 35 U.S.C. § 102(b) as allegedly anticipated by Nakamura et al. (European Application

No. 0456188 A1). In response, Applicant respectfully submits that Nakamura et al. does not specifically teach every element of Applicant's claimed invention.

Initially, Applicant notes that for anticipation to exist, Nakamura et al. must clearly and unequivocally disclose the claimed invention without any need for picking, choosing, or combining various disclosures. In this regard, Applicant respectfully directs the Office's attention to the Board's discussion of anticipation in *Ex parte* Bobsein et al., (Appeal No. 2005-1332, a copy of which is attached), and to *In re Arkley*, 172 U.S.P.Q. 524 (CCPA 1972), which is cited in *Ex parte* Bobsein. Those decisions stand for the proposition that, for anticipation to stand, there must not be picking and choosing among possible combinations.

The final Office Action states that Applicant's stabilizer, arginine, is disclosed in Nakamura et al., referring to column 9, lines 52-58. The cited passage is set forth in its entirety, as follows:

> The therapeutic agents for hepatocirrhosis of the invention <u>may</u> contain other additives such as stabilizers, excipients, dissolution-promoters, adsorption-preventors and antioxidants, and examples thereof include, for example, sugars such as mannitol and glucose, amino acids such as glycine, alanine, lysine and arginine, proteins such as albumin, alcohols such as ethylene glycol and glycerol, hydrophilic polymers such as polyethylene glycol, inorganic salts such as NaCl, organic salts such as sodium citrate, surfactants such as Polysorbate 80 and reducing agents containing sulfur, which may be used alone or in combination.

(EP 0 456 188 A1, column 9, line 52 – column 10, line 6, emphasis added.) The final Office Action refers to the previous Office Action for a description of the other elements of the rejection.

In the previous Office Action (mailed August 18, 2005), the Action states that "Nakamura teaches a lyophilized preparation comprising the following components: 1 mg HGF, 100 ml of phosphate buffer, 0.15 M NaCl (see column 14, lines 25-35)." (Office Action mailed August 18, 2005, page 4, lines 5-7.) The Office Action cites to column 9, line 52 – column 10, line 13 for the disclosure of stabilizing agents. The Office Action thus concludes that "[t]he preparation [of Nakamura] contained 0.01 mg/ml of HGF, and is to be reconstituted at 0.01 mg/ml." (Office Action mailed August 18, 2005, page 4, lines 8-9.) So that there is no question about what Nakamura et al. actually discloses, the passage at column 14, lines 25-35 is reproduced as follows:

> Example 1
> An aqueous solution is prepared aseptically by adding 1 mg of a hepatocyte growth factor and 100 mg of human serum albumin to 100 ml of 0.02 M phosphate buffer (pH 7.4) containing 0.15 M NaCl and 0.01% Polysorbate 80, and filled in a vial at 1 ml per vial, followed by lyophilization and sealing. Injectable distilled water is filled in an ampoule at 1 ml each for dissolution.

(EP 0 456 188 A1, column 14, lines 25-35.)

In addressing the Office Actions' points, Applicant initially respectfully notes that Nakamura et al. is relied upon by the Office for particular elements of Applicant's claims: 1 mg HGF, 100 ml of phosphate buffer, 0.15 M NaCl , and the Office Action specifically refers to column 14, lines 25-35 for that specific disclosure. It is factually incorrect to state that Nakamura teaches a lyophilized preparation "comprising" those components, as the Office Action does. (Office Action mailed August 18, 2005, page 4, lines 5-7.) That disclosure is very specific, and states exactly what is included, described in precise amounts and concentrations.

Applicant also respectfully disagrees with the statements that arginine is described in Nakamura et al. as a stabilizing agent. Arginine, along with glycine, alanine, and lysine, are described as "amino acids," but are not characterized by Nakamura et al. as being anything other than "additives." To be precise, Nakamura et al. describes additives as including stabilizers, excipients, dissolution-promoters, adsorption-preventors, and antioxidants. Nakamura et al. further discloses "examples" of additives as including, for example, sugars, amino acids, proteins, alcohols, hydrophilic polymers, inorganic salts, organic salts, surfactants, and reducing agents. However, Nakamura et al. does not state how the examples correlate with the subclasses of additives that are listed. Thus, while Applicant's specification states that arginine, as well as other amino acids, can be used as stabilizers, that information is not provided by Nakamura et al., and to suggest that Nakamura et al. discloses arginine – or any other particular amino acid – for use as a stabilizer, is factually incorrect.

Applicant respectfully submits that Nakamura et al. does not anticipate the present invention and that the final Office Action has picked and chosen from its disclosure in order to arrive at all of the claimed elements. Applicant notes that Example 1 from Nakamura et al. (column 14, lines 25-35) contains, in addition to the HGF, phosphate buffer, and NaCl identified by the final Office Action, human serum albumin and Polysorbate 80. It does not contain arginine.

Applicant notes that both albumin and Polysorbate 80 are identified in Nakamura et al. as being "additives" that may be contained in the therapeutic agents of Nakamura et al. (Column 9, lines 58 – column 10, line 1 (albumin); column 10, lines 4-5

(Polysorbate 80)). Thus, Nakamura et al. specifically chose certain "additives" – human serum albumin and Polysorbate 80 – but it specifically excluded others. To state that Nakamura et al. discloses a composition having 1 mg HGF, 100 ml of phosphate buffer, 0.15 M NaCl, *and* arginine, is factually incorrect.

The Office is not free to pick and choose from disclosures to arrive at a claimed invention, so as to defeat patentability. The statutes and case law very clearly require a specific disclosure of each element of a claimed invention – all in one place – for anticipation to stand. Nakamura et al. does not provide such disclosure.

Applicant respectfully submits that the claims are not anticipated and respectfully request withdrawal of the rejection for anticipation over Nakamura et al.

The Office Action also rejects claims 1 and 16 under 35 U.S.C. § 102(b) as anticipated by, or in the alternative, under 35 U.S.C. § 103 as obvious over, Nakamura et al.

Applicant respectfully notes that Nakamura et al. has been discussed above in detail, as to the rejection of claim 1 for anticipation. Applicant notes that claim 16 depends from claim 1 and thus, includes all of the same elements as claim 1. To the extent that Applicant's points above were made with regard to the elements recited in claim 1, they are equally applicable to claim 16.

Applicant notes that while the Office Action states that these claims are anticipated by, or in the alternative, obvious over Nakamura et al., the Office Action fails to make any case for the obviousness of these claims. The Office Action fails to address any of the three requirements of a *prima facie* case of obviousness: motivation,

expectation of success, and presence of all claimed elements. For this technical deficiency alone, the rejection should be withdrawn.

However, Applicant additionally notes that a *prima facie* case cannot be made from Nakamura et al. for at least the following reasons. As noted above, the specific compositions disclosed by Nakamura et al. do not include arginine. Moreover, there is nothing in Nakamura et al. that would cause one of ordinary skill in the art to add arginine, or to replace another component of Nakamura et al.'s compositions with arginine. There is no suggestion of its desirability as an additional additive, and thus, there is no reason one of skill in the art would add it to Nakamura et al.'s compositions. Additionally, there is no suggestion of its interchangeability with some other component already present in one of Nakamura et al.'s compositions. For these reasons, there is no reason that a person of skill in the art would select, from all of the choices of "additives" in Nakamura et al., arginine.

Additionally, there is not a reasonable expectation of success in a modification of Nakamura et al. that would result in the presently claimed invention. Applicant respectfully refers the Office to the "Background Art" section of the present specification, which describes at least two published HGF formulations, examples of which are described as including, for example, human serum albumin, mannitol, lysine, arginine, glycine, and alanine, as stabilizing agents. However, each of these formulations is described as being unacceptable: one for lack of long-term stability, and the other for being undesirable for human administration. It is respectfully submitted that modifying or changing the additives in HGF formulations can result in unexpected

results and undesirable final products. Without more, there is no reasonable expectation of success in a modification of Nakamura et al.

For at least these reasons, Applicant respectfully submits that Nakamura et al. does not anticipate or render obvious Applicant's claimed invention, and respectfully requests withdrawal of the rejections for anticipation or obviousness over Nakamura et al.

The Office Action rejects claims 1, 3, 4, and 6-16 under 35 U.S.C. § 103(a) as allegedly unpatentable over Nakamura et al. in view of Tanaka et al. (WO 97/02832).

Applicant has noted above the reasons why Nakamura et al. does not anticipate or render obvious the presently claimed invention. Still further, Applicant respectfully submits that Tanaka et al. fails to supply Nakamura et al.'s missing teachings and also fails to provide motivation to make any change to Nakamura et al. to arrive at the presently claimed invention.

Still further, the Office admits that Nakamura et al. does not disclose Applicant's specifically claimed pH range (see claim 10, for example), but relies upon Tanaka et al. for this missing teaching. However, Applicant respectfully submits that a *prima facie* case of obviousness does not result.

Initially, Applicant notes that there is nothing in Nakamura et al. that would lead to the selection of a different pH than that disclosed, i.e., pH 7.4. While it is not explicitly stated, it is reasonable to conclude that the choice of pH 7.4 was made to closely match physiological pH. However, there is nothing in Nakamura et al. that

would suggest that such pH is undesirable. Thus, there is no reason to turn to the disclosure of Tanaka et al. for the choice of a different pH.

Additionally, if anything, Tanaka et al. teaches away from the present invention, which requires a concentration of less than 5 mg/ml. Tanaka et al. specifically states that the solubility of TGF varies with pH and that the solubility is 0.1 to 5 mg/ml at pH 7, but the solubility is over 20 mg/ml at pH 5. (Tanaka et al., paragraph [0018]). Tanaka et al. then proceeds to state that therefore, "it is *preferred* to keep the pH around 5.0 to 6.0." (Id., emphasis added.) Thus, Tanaka et al. clearly suggests a higher concentration of HGF than 5 mg/ml.

Applicant respectfully submits that a *prima facie* case of obviousness does not result from the combination of Nakamura et al. and Tanaka et al. and respectfully requests withdrawal of the rejection for obviousness.

CONCLUSION

In view of the foregoing, the Examiner is respectfully requested to reconsider and withdraw the objections and rejections of record, and allow each of the pending claims.

Applicant therefore respectfully requests that an early indication of allowance of the application be indicated by the mailing of the Notices of Allowance and Allowability.

Should the Examiner have any questions regarding this Response, the Examiner is invited to contact the undersigned at the below-listed telephone number.

Respectfully submitted,
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte BARRETT RICHARD BOBSEIN,
WILLIAM CHRISTOPHER FINCH,
and
DAVID ALBERT GLEESON

Appeal No. 2005-1332
Application No. 09/774,064

ON BRIEF

Before PAK, WARREN, and TIMM, *Administrative Patent Judges.*

TIMM, *Administrative Patent Judge.*

DECISION ON APPEAL

This appeal involves claims 1 and 3 which are all the claims pending in the application.

We have jurisdiction over the appeal pursuant to 35 U.S.C. § 134.

INTRODUCTION

Claims 1 and 3 stand rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Japanese Published Unexamined Application 05-170,802 to Hoshino et al. published on July 9, 1993 (Hoshino).[1]

The claims stand or fall together (Brief, p. 4). We select claim 1 to represent the issues on appeal. Claim 1 reads as follows:

> 1. A waterborne pigmented paper or paperboard coating composition comprising pigment comprising 50% to 100%, by weight of said pigment, calcium carbonate and from 1% to 25%, as dry weight by weight of said pigment, of an aqueous polymeric dispersion comprising
>
> (c) 95-25% by weight, based on the weight of the solids of said aqueous polymeric dispersion, of a first emulsion polymer having an average particle diameter of 150 to 3000 nanometers and
>
> (d) 5-75% by weight, based on the weight of the solids of said aqueous polymeric dispersion, of a second emulsion polymer having an average particle diameter of 40 to 600 nanometers
>
> wherein the ratio of said average particle diameter of said first emulsion polymer to said average particle diameter of said second emulsion polymer is from 1.2 to 60,
>
> wherein at least said first emulsion polymer particles, when dry, contain at least one void, and wherein said first emulsion polymer is prepared in the presence of said second emulsion polymer or said second emulsion polymer is prepared in the presence of said first emulsion polymer.

Because the Examiner has established a prima facie case of obviousness, we affirm. Our reasons follow.

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[1]We rely upon and cite to the English translation made of record on March 14, 2005.

OPINION

Hoshino describes a waterborne pigmented paper or paperboard coating composition including, among other things, a pigment containing inorganic pigments and emulsion particles as plastic pigments (Hoshino, ¶ 0016, ll. 6-10). Hoshino notes that hard emulsion particles have been studied as additives for coating agents for reducing coating weight, improving gloss, whiteness, opacity, etc. (Hoshino, ¶ 0002, ll. 1-4). According to Hoshino, the industrial use of these emulsion particles as replacements for inorganic pigments such as kaolin, calcium carbonate, talc, satin, etc. in the paper coating field is increasing (Hoshino, ¶ 0002, ll. 4-7).

Hoshino describes emulsion particles with a bimodal particle distribution (Hoshino, ¶ 0009-10). The Examiner finds, and Appellants do not dispute, that the Examples of Hoshino show the claimed proportion and diameters of the two emulsion polymer particles required by claim 1 (Answer, p. 3; Brief and Reply Brief in their entirety). Nor is there any dispute that the emulsion polymer particles of Hoshino meet the other requirements of the aqueous polymeric dispersion recited in claim 1 (Answer, p. 3; Brief and Reply Brief in their entirety). Appellants' arguments focus instead on the calcium carbonate concentration recited in the claim. The issue, therefore, is whether Hoshino sufficiently describes including calcium carbonate in the composition in an amount sufficient to anticipate the composition of the claim or whether there is a sufficient reason, suggestion, or motivation to add calcium carbonate in the claimed amount such that there is a prima facie case of obviousness.

Anticipation

We agree with Appellants that Hoshino does not disclose each and every limitation of claim 1 with sufficient specificity such that the claimed composition is anticipated. In order to anticipate, Hoshino must clearly and unequivocally disclose the claimed invention or direct those skilled in the art to the invention without any need for picking, choosing, and combining various disclosures not directly related to each other by the teachings of the cited reference. *In re Arkley*, 455 F.2d 586, 587, 172 USPQ 524, 526 (CCPA 1972). "Such picking and choosing may be entirely proper in the making of a 103, obviousness rejection, where the applicant must be afforded an opportunity to rebut with objective evidence any inference of obviousness which may arise from the similarity of the subject matter which he claims to the prior art, but it has no place in the making of a 102, anticipation rejection." *Arkley*, 455 F.2d at 587-88, 172 USPQ at 526.

The Examiner's finding of anticipation is based upon the disclosure in Hoshino of a concentration of aqueous polymeric dispersion in the range of 3-30% as a preferred embodiment coupled with a disclosure calcium carbonate in a list of six inorganic pigments. But Hoshino, in fact, does not limit the inorganic pigments to the six compounds specifically recited. What Hoshino states is that "[s]ome examples of the inorganic pigments include kaolin, calcium carbonate, talc, satin white, titanium dioxide, etc." Moreover, the only exemplified composition contains an inorganic pigment mixture of 63 parts of kaolin clay with 27 parts of calcium carbonate. Therefore, mixtures are also contemplated. One of ordinary skill in the art, in fact, is

directed to picking and choosing an inorganic pigment from a much larger genus than acknowledged by the Examiner. Moreover, there is no direct disclosure of a pigment mixture containing an amount of calcium carbonate within the claimed range coupled with an amount of emulsion particles in the claimed range of 1-25%. To obtain the composition of claim 1, one of ordinary skill in the art must both pick and choose among the various acceptable inorganic pigments and conduct some experimentation, albeit routine in nature, with regard to the amount of inorganic pigment and emulsion particles to include in the pigment. Therefore, we find the disclosure of Hoshino lacks the specificity required for a finding of anticipation.

Obviousness

The question of obviousness, however, stands on a different footing. As stated above, picking and choosing within the teachings of the prior art is entirely proper in the context of an obviousness rejection. *Arkley*, 455 F.2d at 587-88, 172 USPQ at 526. Routine experimentation involving such parameters as concentration is also proper in the context of obviousness. *See In re Boesch*, 617 F.2d 272, 276, 205 USPQ 215, 219 (CCPA 1980). Note also *In re Woodruff*, 919 F.2d 1575, 1578, 16 USPQ2d 1934, 1936-37 (Fed. Cir. 1990), and *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Claim 1 requires that calcium carbonate be present in the pigment in an amount of 50-100 weight %. The claim further requires that the aqueous dispersion of emulsion polymers be present in an amount of 1-25%, as dry weight by weight of the pigment. The Examiner finds that Hoshino describes, as a preferred embodiment, including the emulsion polymer particles in

an amount of 3-30% by weight of the pigment and concludes, therefore, that the inorganic pigment must be present in an amount of 70-97% by weight of the pigment in that preferred embodiment (Answer, p. 3). Appellants traverse this finding on the basis that "this is not the literal disclosure of Hoshino." (Brief, p. 4). Appellants' traversal is not persuasive because, even though Hoshino does not say it literally, the disclosure is present. The pigment of Hoshino is a combination of inorganic pigments and the emulsion particles as "plastic pigment" (Hoshino, ¶ 0016, ll. 6-9). The amount of emulsion particles is related in Hoshino as a percentage of the "entire pigments." (Hoshino, ¶ 0017, ll. 1-4). Therefore, the percentage of inorganic pigments is the amount which is not emulsion pigment.[2] We, therefore, find adequate factual support in Hoshino for the finding made by the Examiner, i.e., that Hoshino describes by default including inorganic pigment in an amount of from between 97 and 70% by weight of the entire pigment in the preferred embodiment. That Hoshino includes other less preferred embodiments and examples does not, contrary to the arguments of Appellants (Brief, p. 5), somehow negate the disclosure of the preferred embodiment.

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[2]The words "entire pigments" would be understood by one of ordinary skill in the art to be referring to the combination of emulsion particles as plastic pigments and inorganic pigments. This is the case because inorganic and plastic pigments are the only components that make up the pigment. In fact, the plastic pigments are said to be a replacement for inorganic pigments (Hoshino, ¶ 0002, ll. 4-7). Also note that Hoshino calculates the quantity of other components based on the combined amount of inorganic and plastic pigments (Hoshino, ¶ 0016, ll. 19-22). Moreover, the formulation provided on page 22 of the translation of Hoshino further validates the Examiner's interpretation of the reference as the pigment amounts (clay, calcium carbonate and emulsion particles) add up to 100 parts by weight.

We agree with the Examiner that it would have been obvious to one of ordinary skill in the art to select calcium carbonate as the inorganic pigment in the composition of Hoshino as it is expressly suggested in the reference. It follows then that Hoshino suggests the use of a pigment containing 70-97% by weight calcium carbonate as required by claim 1.

Appellants argue that the Examiner has not met his burden in establishing a prima facie case of obviousness because he has not pointed to any disclosure within Hoshino which indicates a realization of the problem faced by Appellants or which would motivate one skilled in the art to form Appellants' composition (Brief, p. 6). This argument is not persuasive for several reasons. First, the prior art need not address Appellants' problem. *In re Dillon*, 919 F.2d 688, 693, 16 USPQ2d 1897, 1901-1902 (Fed. Cir. 1990)(*en banc*), *cert. denied*, 500 U.S. 904 (1991). Second, Hoshino recognizes both gloss and brightness (whiteness), the properties focused on by Appellants, as important properties to be optimized (Hoshino, ¶ 0008). Third, Hoshino describes dispersions having the bimodal particle composition claimed, describes calcium carbonate as one of the inorganic pigments which can be combined with the emulsion particles and suggests amounts within and/or overlapping those of the claim. Under these circumstances, a case of prima facie obviousness is properly established. Where the difference between the claimed invention and the prior art is some range or other variable within the claims, the applicant must show that the particular range is critical, generally by showing that the claimed range achieves unexpected results relative to the prior art range. *In re Woodruff*, 919 F.2d 1575, 1578, 16 USPQ2d 1934, 1936-37 (Fed. Cir. 1990).

We conclude that the Examiner has established a prima facie case of obviousness with respect to the subject matter of claims 1 and 3 which has not been sufficiently rebutted by Appellants. To the extent that Appellants are relying upon a showing of unexpected results to overcome the prima facie case of obviousness, we note that sufficiently probative objective evidence has not been relied upon in this appeal. Attorney arguments in the brief cannot take the place of evidence. *In re Lindner*, 457 F.2d 506, 508, 173 USPQ 356, 358 (CCPA 1972).

CONCLUSION

To summarize, the decision of the Examiner to reject claims 1 and 3 under 35 U.S.C. § 102(b) or, in the alternative, under 35 U.S.C. § 103(a) is affirmed on the basis of obviousness under § 103(a).

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED

CHUNG K. PAK Administrative Patent Judge	)
CHARLES F. WARREN Administrative Patent Judge	) BOARD OF PATENT) APPEALS) AND) INTERFERENCES
CATHERINE TIMM Administrative Patent Judge	)

CT/jrg

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